



Medical Services Advisory Committee

Public Summary Document

Reference No. 36 – Nationally Funded Centres - Peritonectomy with heated intraoperative intraperitoneal chemotherapy

Sponsor: Australian Health Ministers' Advisory Council via its Nationally Funded Centres Reference Group

Date of MSAC consideration: 48th MSAC meeting, 29-30 March 2010

1. Purpose of Application

The Nationally Funded Centres (NFC) Program provides a national policy for public sector provision of high cost, highly specialised clinical services and technologies with limited demand.

In its 2006 report to the Australian Health Ministers' Advisory Council (AHMAC), MSAC recommended that a NFC undertake research and evaluation to determine the effectiveness of peritonectomy. No NFC was established but the procedure is being conducted at several Australian sites, one of which carries out the majority of these procedures.

In December 2008, AHMAC, via its NFC Reference Group, requested MSAC to undertake a reassessment of peritonectomy for pseudomyxoma peritonei and peritoneal mesothelioma (previously assessed by the MSAC in 2006), to:

- a) provide an update on the previous, 2006 assessment of peritonectomy for NFC status;
- b) comment on the number of NFC sites, if any, that are needed; and
- c) develop criteria to assist in making NFC site decisions should AHMAC decide to confer NFC status on this technique.

2. Current arrangements for public reimbursement

Peritonectomy is not listed on the Medicare Benefits Schedule.

3. Background

Peritonectomy with heated intraoperative intraperitoneal chemotherapy (HIPEC) is a high cost, low demand procedure with high mortality and complication rates. Peritonectomy is a surgical procedure performed for the treatment of peritoneal neoplasms whose purpose is to remove all visible peritoneal tumour deposits. Abdominal organs, such as the spleen are often removed in order to complete cytoreduction. It is an extensive procedure that takes approximately 8–12 hours to perform. Peritonectomy can be performed in combination with HIPEC and is often followed by early postoperative intraperitoneal chemotherapy (EPIC), systemic chemotherapy or both. HIPEC involves perfusing the abdominal cavity with heated (40–48°C) fluid containing a chemotherapeutic agent for 60–90 minutes after the peritonectomy but before the joining of anastomoses. Peritonectomy may be performed for metastatic colorectal, ovarian and other cancers. The consideration of this review relates only to pseudomyxoma peritonei and peritoneal mesothelioma.

4. Clinical need

Pseudomyxoma peritonei

Pseudomyxoma peritonei (PMP) is often defined as a rare neoplastic disorder of low malignant potential which originates from a tumour in the appendix and slowly spreads throughout the abdominal cavity, resulting in mucinous ascites (Bryant et al 2005) (“jelly belly”).

Nomenclature of PMP is not standardised, and the pathophysiology and natural history of the condition are poorly understood.

The quality of life of patients with PMP may be affected by the bulk of the tumour, and the disease is fatal if left untreated. Patients with PMP may survive for several years after diagnosis, as the progression of the disease is slow. Patient survival is variable, but with palliative surgery and systemic chemotherapy, median survival has been reported as between 5 and 10 years.

This assessment focuses on the PMP patient group uniformly agreed as comprising PMP, that is, those with a condition of mucus accumulation within the abdominal cavity caused by a borderline malignant adenoma of appendiceal origin (disseminated peritoneal adenomucinosis, DPAM). Patients with mucinous ascites due to other tumour types are variably considered as having PMP by different authors.

Peritoneal mesothelioma

Peritoneal mesothelioma is a primary malignancy of mesothelial cells of the peritoneum. In general, people diagnosed with mesothelioma do not survive more than two years following diagnosis. Mesothelioma may be classified histologically as sarcomatoid, epithelioid or mixed; those with epithelioid mesothelioma have a better prognosis. Peritoneal mesothelioma represents fewer than one tenth of all cases of mesothelioma in Australia. The death of patients with peritoneal mesothelioma is usually due to progression of the disease in the peritoneal cavity, in particular the involvement of the bowel or intractable ascites.

5. Comparator

Current treatment for patients with these conditions is to debulk the abdomen of fluid on repeated occasions, as well as remove some abdominal organs (e.g. spleen and portions of the bowel). Comparative data on the safety and effectiveness of peritonectomy with HIPEC versus current alternative therapies remains lacking. The previous MSAC assessment discussed the need for further evaluation.

6. Safety

MSAC noted there were no comparative studies of peritonectomy versus an alternative treatment, or of peritonectomy with HIPEC versus peritonectomy with contemporary systemic chemotherapy. As a result of the poor quality of existing studies, mortality and morbidity rates are not certain. However, the procedure is associated with potentially high rates of mortality and morbidity, including complications requiring reoperation and many patients having to undergo repeat procedures, in some cases multiple times.

7. Clinical effectiveness

Peritonectomy with HIPEC is performed with the intent of providing a curative treatment for peritoneal neoplasms. MSAC found that the evidence for the effectiveness of peritonectomy with HIPEC in the treatment of PMP (DPAM) and peritoneal mesothelioma remains weak. This is due to a lack of high-level evidence. 52-96% of pseudomyxoma peritonei patients achieved five-year survival rates (across six studies). Median survival ranged from 51 to 156 months across three studies. The five-year survival rate for peritoneal mesothelioma patients varied from 29-59% across five studies. Median survival ranged from 34 to 92 months (four studies), and was not reached in two studies.

8. Cost-effectiveness

An estimated cost of just over \$100,000 per patient was calculated as part of an economic evaluation, however MSAC found that the cost estimates provided were incomplete and require revision. MSAC noted that the procedure is currently being funded through various means, depending on whether patients are public or private.

9. Summary of consideration and rationale for MSAC's advice

MSAC found insufficient evidence in relation to safety, effectiveness and cost-effectiveness of peritonectomy with HIPEC for the treatment of patients with the rare diseases of pseudomyxoma peritonei or peritoneal mesothelioma. The only clinical evidence available on this procedure in these specific diseases comprises non-comparative case series from Australia and overseas. MSAC was therefore concerned about recommending a NFC for this procedure where so little is known, and improved patient outcomes could not be assured.

Due to the relatively low demand for this service, it has been proposed that a single specialist centre could meet expected demand, provide a higher quality service, improve patient outcomes, increase expertise in the field, and undertake research and evaluation in the Australian setting. However, MSAC did not consider that providing a NFC for peritonectomy with HIPEC would result in all Australian patients being referred to the one centre, and may be a barrier to some patients who could not travel interstate/intrastate.

MSAC noted that peritonectomies are done in the United Kingdom, United States of America and Europe, with much larger populations undergoing the HIPEC procedure compared to the Australian context. As more data are accumulated, this international experience, together with the continuing Australian experience, will help inform the evidence base for Australian clinicians.

10. MSAC's advice to AHMAC

After considering the strength of the available evidence in relation to safety, effectiveness and cost-effectiveness, MSAC did not support the establishment of a Nationally Funded Centre to provide peritonectomy with heated intraoperative intraperitoneal chemotherapy to treat pseudomyxoma peritonei or peritoneal mesothelioma. MSAC suggests that further clinical trials or other means by which the clinical evidence base could be proactively evaluated, may better inform future decisions regarding the public funding of this service.

11. Context for Decision

MSAC's fourth term of reference is to undertake health technology assessment work referred by AHMAC and report its findings to AHMAC.

12. Linkages to Other Documents

MSAC's processes are detailed on the MSAC Website at: www.msac.gov.au.

The MSAC Assessment Report is available at [*link when published and agreed by AHMAC to publicly release outcomes*].